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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/652,282	08/30/2000	Maurice Kent Gately	9483	2369

7590 03/11/2002

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[REDACTED] EXAMINER

DECLOUX, AMY M

ART UNIT	PAPER NUMBER
1644	95

DATE MAILED: 03/11/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No. 09/652,282	Applicant(s) Gately And Presky
Examiner DeCloud, Amy	Art Unit 1644

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1)  Responsive to communication(s) filed on Nov 9, 2001
- 2a)  This action is FINAL. 2b)  This action is non-final.
- 3)  Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle* 835 C.D. 11; 453 O.G. 213.
- Disposition of Claims
- 4)  Claim(s) 1-5, 14-20, and 29 is/are pending in the application
- 4a) Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5)  Claim(s) \_\_\_\_\_ is/are allowed.
- 6)  Claim(s) 1-5, 14-20, and 29 is/are rejected.
- 7)  Claim(s) \_\_\_\_\_ is/are objected to.
- 8)  Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9)  The specification is objected to by the Examiner.
- 10)  The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- 11)  The proposed drawing correction filed on \_\_\_\_\_ is: a)  approved b)  disapproved.
- 12)  The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. § 119

- 13)  Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a)  All b)  Some\* c)  None of:
1.  Certified copies of the priority documents have been received.
  2.  Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3.  Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \*See the attached detailed Office action for a list of the certified copies not received.
- 14)  Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

### Attachment(s)

- 15)  Notice of References Cited (PTO-892) 18)  Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 16)  Notice of Draftsperson's Patent Drawing Review (PTO-948) 19)  Notice of Informal Patent Application (PTO-152)
- 17)  Information Disclosure Statement(s) (PTO-1449) Paper No(s). 11 20)  Other: \_\_\_\_\_

## DETAILED ACTION

1. Note The examiner of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Amy DeCloux, Group Art Unit 1644, Group 1640, Technology Center 1600.
2. Applicants' amendment, sequence listing, associate power of attorney and supplemental IDS filed 11/9/01 (Paper No. 8-11), are acknowledged.

Claims 1-5, 14-20 and 29 are pending.

Applicant is in sequence compliance.

Formal drawings and/or photographs have been submitted which fail to comply with 37 CFR 1.84. Please see the enclosed form PTO-948.

### INFORMATION ON HOW TO EFFECT DRAWING CHANGES

#### A). Correction of Informalities -- 37 CFR 1.85

New corrected drawings must be filed with the changes incorporated therein. Identifying indicia, if provided, should include the title of the invention, inventor's name, and application number, or docket number (if any) if an application number has not been assigned to the application. If this information is provided, it must be placed on the front of each sheet and centered within the top margin. If corrected drawings are required in a Notice of Allowability (PTOL-37), the new drawings MUST be filed within the THREE MONTH shortened statutory period set for reply in the "Notice of Allowability."

Extensions of time may NOT be obtained under the provisions of 37 CFR 1.136 for filing the corrected drawings after the mailing of a Notice of Allowability. The drawings should be filed as a separate paper with a transmittal letter addressed to the Official Draftsperson.

#### B) Corrections other than Informalities Noted by Draftsperson on form PTO-948.

All changes to the drawings, other than informalities noted by the Draftsperson, MUST be made in the same manner as above except that, normally, a highlighted (preferably red ink) sketch of the changes to be incorporated into the new drawings MUST be approved by the examiner before the application will be allowed. No changes will be permitted to be made, other than correction of informalities, unless the examiner has approved the proposed changes.

#### Timing of Corrections

Applicant is required to submit acceptable corrected drawings within the time period set in the Office action. See 37 CFR 1.85(a). Failure to take corrective action within the set period will result in ABANDONMENT of the application.

3. The rejections of record can be found in the previous Office Action, mailed 5-9-01 (Paper No. 6).

In view of applicant's amendment and remarks filed 11/9/01, the 112 second paragraph rejection, the 102 (b) rejections anticipated by Presky et al. and by Cytokine Bulletin (Genzyme), and the 103 rejections over the Cytokine Bulletin have been withdrawn. However, the 102(e) rejection anticipated by Trinchieri et al, the 103 (a) rejection over Trinchiera et al., and the obviousness-type double patenting have been maintained.

4. MAINTAINED Claims 1-4 and 29 are rejected under 35 USC (102 (e) as being anticipated by Trinchiera et al (US Patent 5,811,523), as evidenced by Gately et al (US Patent 5,780,597) and Carter et al (IDS reference "C16").

Applicants acknowledge that though claim 3 of Trinchieri et al recites an antibody that reacts with IL-12 heterodimer and reacts with the 30-35 KD IL-12 subunit and that nothing in the Trinchieri patent is inconsistent with the presently claimed subject matter, applicants traverse the rejection on the grounds that this is not enough to anticipate the claims. The examiner notes that the Office is not equipped to manufacture the claimed antibodies and/or the referenced antibodies, nor to conduct comparisons, the burden is on the applicant to establish a patentable distinction between the claimed and referenced fusion proteins. See *In re Best*, 195 USPQ 430, 433 (CCPA 1977). Therefore, though applicant's arguments have been carefully considered, they are not deemed persuasive and the rejection is maintained, essentially for the reasons of record.

5. MAINTAINED Claims 1, 5, 14, 18 and 20 are rejected under 35 USC (103 (a) as being obvious over Trinchieri et al (US Patent 5,811,523), in view of Gately et al (US Patent 5,780,597) and in view of Bendig (Methods:A Companion to Methods in Enzymology Vol. 8:83-93, 1995) and admissions in the specification on page 16, last paragraph.

Applicants traverse the rejection on the grounds that Trinchieri has deficiencies which are not cured by Bendig who teaches methods of humanization of antibodies, because Trinchieri differ from the claimed antibodies in ways other than the fact that the Trinchieri antibodies are not humanized. However as discussed supra, the putative Trinchieri deficiencies have not been validated. Therefore, though applicant's arguments have been carefully considered, they are not deemed persuasive and the rejection is maintained, essentially for the reasons of record.

7. MAINTAINED Claims 1-5, 14-20 and 29 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-23 of US Patent No.6,225,117.

Applicant has deferred addressing said rejection, therefore, said rejection is maintained essentially for reasons of record.

8. No claim is allowed.

9. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy DeCloux whose telephone number is (703) 306-5821. The examiner can normally be reached Monday through Friday from 9:00 am to 6:00 pm. a message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-3014.

Amy DeCloux, Ph.D.  
Patent Examiner,  
Group 1640, Technology Center 1600  
March 8, 2002

*David A. Saunders*  
DAVID SAUNDERS  
PRIMARY EXAMINER  
ART UNIT 1644